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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Martin O'Sullivan

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EXAMINER

ROANE, AARON F

ART UNIT

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3769

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/622,221	<b>Applicant(s)</b> O'SULLIVAN ET AL.	
	<b>Examiner</b> AARON ROANE	<b>Art Unit</b> 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,9-17,19 and 22-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,9-17,19 and 22-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/18/2010</u> . | 6) <input type="checkbox"/> Other: _____  |

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/18/2010 has been entered.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 9-17, 19 and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (U.S. Patent 6,161,543) in view of Whayne et al. (U.S. Patent 6,203,525 B1) in further view of Fleischman (U.S. Patent 5,885,278).

Regarding claims 1, 2 and 17, Cox et al. disclose a catheter for ablating tissue via cryogenic or RF energy delivery, the catheter comprising an elongated generally-tubular

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catheter body (66 in figure 4 and its analogous counterparts in other embodiments) having proximal and distal ends; and an ablation assembly (distal portion of 66 including 70, see figure 4 and its analogous counterparts in other embodiments) at the distal end of the catheter body, the ablation assembly including a generally-straight ablation arrangement that is generally transverse to the catheter body (see figures 4, 6A-D, 24, 27, 28, 33, 34 and 45), the ablation arrangement comprising: a non-conductive tubing (distal tubing 89 in figures 7 and 8A-C and its analogous counterpart in other embodiments) mounted on-the distal end of the catheter, the non-conductive tubing has a pre-formed generally heel-shaped curve comprising a first bend away from the axis of the catheter body and a second bend back toward and past the axis of the catheter body and terminates in a generally straight distal end which end is generally transverse to the axis of the catheter body. It should further be noted that Cox et al. disclose the generally straight distal end of the non-conductive tubing forms an angle with the axis of the catheter body ranging from about 75° to about 110°, this is easily seen by a single example in which Cox et al. disclose the generally straight distal end being at angle of 90 with respect of the axis catheter body, see figures 5 and 9 col. 13:54 – col. 14:6 and “as best viewed in FIG. 12A, the upper section segment 162 (half of the longitudinal right atrial lesion 50) is formed using a right angle probe 163 (FIG. 24) having a first elbow portion 166 positioned between the generally straight elongated shaft 66 and the generally straight ablating end. The first elbow portion has an arc length of about 85° to about 95° and a radius of curvature of about 3.2 mm to about 6.4 mm. The ablating end 70 is preferably about 2.0 mm to about 4.0 mm in diameter, and about 2.0 cm to about 6.0 cm in length.

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In this configuration, the ablating surface 65 extends, circumferentially, from a distal end 165 thereof to just past an elbow portion 166 of the right angle probe 163,” see col. 17:64 – col. 18:15 and figures 12A and 24 specifically. **Finally, Cox et al. disclose that the distal end of the catheter is free.** Although, Cox et al. fail to disclose that the ablation assembly is a porous electrode, Cox et al. do disclose the use of various alternative/equivalent ablation energy delivery forms/means including cryogenic and RF, see col. 3, lines 36-44. Cox et al. further fails to explicitly disclose the recited central longitudinal axis and the angular relationship therebetween. Whayne et al. disclose a catheter for ablating tissue and teach providing the device with a porous electrode assembly (362 in figure 36-39) mounted on non-conductive tubing (distal tubing 28 in figure 3A and its analogous counterpart 370 in the embodiment illustrated in figure 36), comprising a porous sleeve (364) mounted in surrounding relation to the one or more electrodes; and one or more irrigation openings (374) fluidly connecting the open space to a lumen (lumen of 370) extending through the catheter through which fluid can pass; wherein, in use, fluid passes through the lumen in the catheter, through the one or more irrigation openings, into the open space and through the porous sleeve, see col. 5, 6 and 21-23 and figures 1 and 36-39. Whayne et al. further disclose the one or more electrodes comprises a single coiled electrode (22/372) wrapped around a portion of the non-conductive tubing, see col. 5-8 and 23. Fleischman discloses structures for deploying movable electrode elements for ablating the heart and teaches providing the device with an elongated member 22 having a first bend away from the central longitudinal axis and a second more distally placed bend which allows for the generally straight distal end of the

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elongated member to cross the first central axis at about a right angle in order to provide the ablating elongated member with the proper shape that corresponds to the tissue surface, see figure 17 and 19. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Cox et al., as taught by Whayne et al., to provide a porous electrode assembly located at the distal end of the catheter to serve as an RF ablation electrode in or to form lesions on the tissue, and as further taught by Fleischman, to provide the device with an elongated member having a first bend away from the central longitudinal axis and a second more distally placed bend which allows for the generally straight distal end of the elongated member to cross the first central axis at about a right angle in order to provide the ablating elongated member with the proper shape that corresponds to the tissue surface.

Regarding claims 4 and 19, Cox et al. in view of Whayne et al. in further view of Fleischman disclose the claimed invention, Whayne et al. further disclose the porous sleeve has proximal and distal ends that are bonded to the non-conductive tubing, see figure 38.

Regarding claims 9, 10, 22 and 23, Cox et al. in view of Whayne et al. in further view of Fleischman disclose the claimed invention, Whayne et al. further the porous sleeve comprises a polytetrafluoroethylene (PTFE), see col. 21 and 22. Whayne et al. fail to explicitly disclose the polytetrafluoroethylene (PTFE) is expandable to no more than 10% at a distilled water flow rate of 30 to 40 cc/min. However, when the structure recited in

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the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01 ). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim except a property or function and the examiner can not determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof as in *In re Fitzgerald*, 619 F.2d 67, 70 205 USPQ 594,596 (CCPA 1980). In the present case, the reference has met the structural requirements of the claim as the porous sleeve comprises a polytetrafluoroethylene (PTFE).

Regarding claims 11 and 24, Cox et al. in view of Wayne et al. in further view of Fleischman disclose the claimed invention, Wayne et al. further disclose the porous sleeve comprises a material selected from the group consisting of porous nylon, sintered ceramics, woven meshes and cellular foam, see col. 22, line 39-57.

Regarding claims 12, 13, 25 and 26, Cox et al. in view of Wayne et al. in further view of Fleischman disclose the claimed invention, Wayne et al. disclose the claimed invention, see col. 23:16-54.

Regarding claims 14 and 27, Cox et al. in view of Wayne et al. in further view of Fleischman disclose the claimed invention, Wayne et al. further disclose the electrode assembly further comprises one or more ring electrodes (the right electrode 372 in figures

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37 and 38) mounted proximal and/or distal to the porous electrode (the left and center electrodes 372 in figures 37 and 38).

Regarding claims 15, 16, 28 and 29, Cox et al. in view of Whayne et al. in further view of Fleischman disclose the claimed invention, Whayne et al. further disclose the electrode assembly further comprises one or more temperature sensors (see for example 292 figure 29), wherein the one or more temperature sensors are mounted under the porous sleeve, see col. 23-25 and figure 29.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (U.S. Patent 6,161,543) in view of Whayne et al. (U.S. Patent 6,203,525 B1) in further view of Fleischman (U.S. Patent 5,885,278) as applied to claim 28 above, and further in view of Fung et al. (U.S. Patent 6,120,476).

Regarding claims 30 and 31, Cox et al. in view of Whayne et al. Fleischman disclose the claimed invention except that a pre-shaped support wire made of nitinol extends through a second lumen of the non-conductive tubing. Whayne et al. clearly discloses a first lumen (lumen of 370) used for irrigation, see col. 5, 6 and 21-23 and figures 1 and 36-38. Whayne et al. also disclose the use of a nitinol pre-shaped support wire (26) located in a lumen of a non-conductive tubing (28 and/or 28'). Finally, Whayne et al. clearly disclose an embodiment wherein the distal end of the support wire (26) is fixed within the non-conductive tubing (see portion 158 in figure 14), see col. 12 and figure 14. However,



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Whayne et al. do not disclose simultaneously disposing a nitinol pre-shaped support wire in one lumen of the non-conductive tubing and the having an irrigating pathway/passage in other separate lumen. Fung et al. disclose an irrigated tip-catheter that has at least two lumens and teach the provision of the non-conductive tubing (19) upon which electrodes (38) are placed with three lumens 30, 32 and 34, see col. 4-6 and figure 3. Additionally, Fung et al. teach the simultaneous provision of a pre-shaped nitinol wire (42) placed in one lumen (32) in order to provide steerability/deflection of the device and the use of another lumen (34) as an irrigation lumen in order to provide infusion, see col. 4-6 and figure 3. Therefore, at the time of the invention it would have been obvious to modify the invention of Cox et al. in view of Whayne et al. in further view of Fleischman, as taught by Fung et al., to simultaneously provide the pre-shaped nitinol wire placed in one lumen in order to provide steerability/deflection of the device and the use of another lumen as an irrigation lumen in order to provide infusion.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (U.S. Patent 6,161,543) in view of Whayne et al. (U.S. Patent 6,203,525 B1) in further view of Fleischman (U.S. Patent 5,885,278) as applied to claim 17 above, and further in view of Swanson et al. (U.S. Patent 5,961,513).

Regarding claim 32, Cox et al. in view of Whayne et al. in further view of Fleischman disclose the claimed invention except for reciting the one or more irrigation openings are located only on the side of the porous electrode that is to be in contact with tissue to be

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ablated. It is well known in the art to place or provide holes/pores of a porous material in a particular pattern and/or on a side of the otherwise porous material in order to achieve a particular ablation pattern. Swanson et al. disclose a tissue heating and/or ablating device and teach providing the expandable porous element (22) with holes/pores located on one side in order to achieve a particular ablation pattern and/or serve as a sensing surface, see col. 5-21 and figures 1-14. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Cox et al. in view of Whayne et al. in further view of Fleischman, as is known in the art and taught by Swanson et al., to provide the expandable porous element with holes/pores located on one side in order to achieve a particular ablation pattern and/or serve as a sensing surface.

### ***Response to Arguments***

Applicant's arguments filed 10/18/2010 have been fully considered but they are not persuasive.

Regarding Applicant's arguments/remarks on page 8, 2<sup>nd</sup> paragraph with respect to the primary reference Cox et al., the examiner strongly disagrees and simply cites figures 4, 6, 19A, 20A, 21, 32, 33 and 45, which very clearly disclose "a first bend away from the axis of the catheter body and a second bend distal the first bend back toward and past the axis of the catheter body."

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Regarding Applicant's arguments/remarks on page 8, last three lines through page 9, line 14 with respect to the Fleischman reference, a secondary reference, Applicant asserts that "Fleischman nowhere teaches or suggests a tubing having a pre-formed curve that terminates in a generally straight distal end." This assertion is off the mark, as the Fleischman patent is used to teach/motivate the use of the particular configurations of the recited central longitudinal axis. It should be noted that all three references have distal electrical ablation elements and Fleischman is used to provide the concrete realization of the first and second central longitudinal axis. The fact that Fleischman (and for that matter Whayne et al.) use stylets, tethers or ties to facilitate the shape of the electrode carrying portions or the catheters is irrelevant as the specific shape of the electrode carrying portion (and hence the configuration of the first and second central longitudinal axis) is what and why Fleischman is relevant.

Moreover, with respect to these first two arguments/remarks, which are attacks against the individual references, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the

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person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

Next, it is plainly obvious that both figures 17 and 19 of Fleischman disclose a **generally** straight electrode element 28 having a central longitudinal axis that crosses the central longitudinal axis of the proximal portion of the electrode element 28 proximal the first bend.

Regarding the “pre-formed curve” discussed on page 9, beginning of the last paragraph through page 10, line 7, the examiner has interpreted “pre-formed curve” by giving it the broadest reasonable meaning within the art a curve provided with a shape at some indefinite earlier time. The examiner is not narrowly interpreting “pre-formed curve” as only a permanent curve or rigid curve.

Next regarding Applicant’s arguments/remarks on page 10, 2<sup>nd</sup> full paragraph through page 11, last full paragraph, with respect to the examiner’s earlier response to arguments as it pertains to the change of form or shape and the Dailey case law, the examiner has removed all reference to the rational and/or form, shape and Dailey case as it only clutters up the matters before us now. It should be noted the change of form or shape and the Dailey case law were not relied upon for any rejections in the previous office action or the present.

Again, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a

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conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference.

**Finally, Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.**

**Due to the RCE, this action is made non final.**

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571)272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/  
Examiner, Art Unit 3769